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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,074	10/07/2003	Eric B. Kmiec	41428-0118	7677

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EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,074	KMIEC ET AL.	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a method for identifying a cell having a desired oligonucleotite-directed sequence alteration at a first nucleic acid target site within the cell, the method comprising:

identifying said desired sequence alteration in cells that have been selected for the presence of a selectable phenotype conferred by a concurrent oligonucleotide-directed sequence alteration at a second nucleic acid target site within said cells, classified in class 435, subclass 440, for example.

II. Claims 8-20, drawn to a kit comprising first and second oligonucleotides, classified in class 536, subclass 24.3, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the oligonucleotides of Group II can be used to amplify a particular gene from genomic DNA, rather than in the method of Group I.

Searching the inventions of Groups I and II together would impose serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the oligonucleotides and the method of using them are not coextensive. The search for oligonucleotides of Group II encompasses a

search for any two polynucleotides, each one of which with any sequence. The search for Group II requires a search for the method of effecting a sequence alteration in a cell using oligonucleotides. Therefore, prior art which teaches oligonucleotides of Group II would not necessarily be applicable to the method of Group I. Moreover, even if the oligonucleotide product were known, the method of diagnosis using the product may be novel and unobvious in view of the preamble or active steps.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process

Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. This application contains claims directed to the following patentably distinct species:

Group I

Species of selectable phenotype

A) antibiotic resistance (claim 3, in part),

B) prototrophy (claim 3, in part),

C) expression of a fluorescent protein (claim 3, in part),

D) presence of an epitope (claim 3, in part),

E) resistance to an apoptotic signal (claim 3, in part).

Species of the first and second nucleic acid molecule

F) the nucleic acid molecule comprising the first nucleic acid target does not comprise the second nucleic acid target (claim 4),

G) the nucleic acid molecule comprising the first nucleic acid target comprises the second nucleic acid target (claim 5).

Species of a cell

H) cell is a prokaryotic cell (claim 7, in part),

I) cell is a fungal cell (claim 7, in part),

J) cell is a plant cell (claim 7, in part),

K) cell is an animal cell (claim 7, in part),

L) cell is a mammalian cell (claim 7, in part).

Group II

Species of cellular repair protein

A) cellular repair protein is RAD10 (claim 14, 17, 18, in part),

B) cellular repair protein is RAD51 (claim 14, 17, 18, in part),

C) cellular repair protein is RAD52 (claim 14, 17, 18, in part),

D) cellular repair protein is RAD54 (claim 14, 17, 18, in part),

E) cellular repair protein is RAD55 (claim 14, 17, 18, in part),

F) cellular repair protein is MRE11 (claim 14, 17, 18, in part),

G) cellular repair protein is PMS1 (claim 14, 17, 18, in part),

H) cellular repair protein is XRS2 (claim 14, 17, 18, in part).

Species of further components

I) HDCA inhibitor (claim 15, in part),

J) hydroxyurea ((claim 15, in part),

K) lambda phage beta protein (claim 15, in part).

Species of a cell

L) cell is a prokaryotic cell and has increased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 17, in part),

M) cell is a fungal cell and has increased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 17, in part),

N) cell is a plant cell and has increased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 17, in part),

O) cell is an animal cell and has increased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 17, in part),

P) cell is a mammalian cell and has decreased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 18, in part),

Q) cell is a prokaryotic cell and has decreased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 18, in part),

R) cell is a fungal cell and has decreased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 18, in part),

S) cell is a plant cell and has decreased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 18, in part),

T) cell is an animal cell and has decreased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 18, in part),

U) cell is a mammalian cell and has decreased levels of activity of at least one protein selected from the group consisting of: RAD10, RAD52, RAD52, RAD54, RAD55, MRE11, PMS1 and XRS2 (claim 11, 16 and 18, in part).

Species of selectable phenotype

V) antibiotic resistance (claim 9, in part),

W) prototrophy (claim 9, in part),

X) expression of a fluorescent protein (claim 9, in part),

Y) presence of an epitope (claim 9, in part),

Z) resistance to an apoptotic signal (claim 9, in part).

The species are independent or distinct because they are drawn to different methods of phenotype detection, different cell types and different cellular proteins which are not obvious over each other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 8 and 12 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. For example, if Group I is elected, Applicants need to select one species from each of the groups of species. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
4/28/06